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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 178**

**[Docket No. 98F-1034]**

**Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the expanded safe use of naphthalene sulfonic acid-formaldehyde condensate, sodium salt as an emulsifier in vinylidene chloride copolymer or homopolymer coatings applied to polypropylene films and polyethylene phthalate films intended for use in contact with food. This action is in response to a petition filed by Solvay S.A.

**DATES:** This regulation is effective (*insert date of publication in the Federal Register*). Submit written objections and requests for a hearing by (*insert date 30 days after date of publication in the Federal Register*).

**ADDRESSES:** Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3081.

**SUPPLEMENTARY INFORMATION:** In a notice published in the **Federal Register** of December 2, 1998 (63 FR 66549), as corrected (64 FR 1023, January 7, 1999), FDA announced that a food additive petition (FAP 9B4634) had been filed by Solvay S.A., c/o Keller and Heckman LLP, cf99109

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1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposed to amend the food additive regulations in § 178.3400 *Emulsifiers and/or surface active agents* (21 CFR 178.3400) to provide for the expanded safe use of naphthalene sulfonic acid-formaldehyde condensate, sodium salt as an emulsifier in vinylidene chloride copolymer or homopolymer coatings applied to polypropylene films and polyethylene phthalate films intended for use in contact with food.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that: (1) The proposed use of the additive is safe, (2) the additive will achieve its intended technical effect, and therefore, (3) the regulations in § 178.3400 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP 9B4634 (63 FR 66549). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the provisions of the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time on or before (*insert date 30 days after date of publication in the Federal Register*), file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the

regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

#### **List of Subjects in 21 CFR Part 178**

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 178 is amended as follows:

#### **PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS**

1. The authority citation for 21 CFR part 178 continues to read as follows:

**Authority:** 21 U.S.C. 321, 342, 348, 379e.

2. Section 178.3400 is amended in the table in paragraph (c) by alphabetically adding an entry under the headings “List of substances” and “Limitations” to read as follows:

#### **§ 178.3400 Emulsifiers and/or surface active agents.**

\* \* \* \*

(c) \* \* \*

List of substances	Limitations
Naphthalene sulfonic acid-formaldehyde condensate, sodium salt (CAS Reg. No. 9084-06-4).	<p>For use only:</p> <ol style="list-style-type: none"> <li>1. At levels not to exceed 10 micrograms/in<sup>2</sup> (0.16 mg/dm<sup>2</sup>) in vinylidene chloride copolymer or homopolymer coatings applied to films of propylene polymers complying with § 177.1520 of this chapter.</li> <li>2. At levels not to exceed 14 micrograms/in<sup>2</sup> (0.21 mg/dm<sup>2</sup>) in vinylidene chloride copolymer or homopolymer coatings applied to films of polyethylene phthalate polymers complying with § 176.1630 of this chapter.</li> </ol>

\* \* \* \* \*

Dated: 8/10/99  
August 10, 1999

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

*Jan Windsor*

*L. Robert Lake*

L. Robert Lake  
Director  
Office of Policy, Planning  
and Strategic Initiatives  
Center for Food Safety and Applied Nutrition

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